K072253

OCT 12 2007

5 **510(k) Summary – Revised 09/2007**

510(k) Summary	
Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Susan Lewandowski Manager, Spine Regulatory Affairs Telephone: 610-719-5712 Facsimile: 610-719-5102 Email: lewandowski.susan@synthes.com
Date Prepared:	September 14, 2007
Trade Name:	Synthes SynFix™-LR
Classification:	21 CFR 888.3080 – Intervertebral body fusion device Class II (special controls) Orthopaedic and Rehabilitation Devices Panel (87) Product Code MAX (orthosis, spinal intervertebral fusion)
Predicates:	K062083 Synthes SynFix™-LR P950002 BAK Intervertebral Body Fusion Device
Device Description:	The Synthes SynFix™-LR is a combination radiolucent and radiopaque intervertebral body fusion device. Four screws are inserted through the anteriorly-located plate into the adjacent vertebral bodies. The screws lock securely to the plate using a tapered-thread locking mechanism. The Synthes SynFix™-LR is available as assembled components in various heights and geometries to suit individual pathology and anatomical conditions.
Intended Use/ Indications for Use:	The Synthes SynFix™-LR is a stand-alone anterior interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The interior of the spacer component of the SynFix™-LR can be packed with autograft. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.
Comparison of the device to predicate device(s):	The Synthes SynFix™-LR is substantially equivalent to the predicates in design, function, material, and intended use.
Performance Date (Nonclinical and/or	*Non-Clinical Performance and Conclusions:*

Clinical):	Bench testing results demonstrate that the Synthes SynFix™-LR is substantially equivalent to the predicate devices. *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Synthes Spine
% Ms. Susan Lewandowski
Manager, Spine Regulatory Affairs
1302 Wrights Lane East
West Chester, PA 19380

SEP 12 2011

Re: K072253
Trade/Device Name: SynFix™-LR
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: September 17, 2007
Received: September 18, 2007

Dear Ms. Lewandowski:

This letter corrects our substantially equivalent letter of October 12, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072253

Device Name: SynFix™-LR

Indications For Use:

The SynFix-LR device is a stand-alone anterior interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The interior of the spacer component of the SynFix-LR can be packed with autograft.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucholz

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072253